



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

96 OCT 1 002000T 25 P2:22

Mr. Lin Yan  
Scientific and Regulatory Affairs  
KT Natural Products, Inc.  
1528 Devonwood Drive  
Springfield, Illinois 62704

Dear Mr. Yan:

This is in response to your letter of September 20, 2000 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that KT Natural Products, Inc. is making the following claims, among others, for the product **MiracleHerb-GP™**:

- "Maintain normal cholesterol and triglyceride levels"
- "Maintain a healthy blood pressure"
- "Decrease vascular resistance and increase coronary blood flow"
- "Reduce vascular plaque"
- "Maintain normal blood glucose level"
- "Preserve immunocompetence"

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggest that it is intended to treat, prevent, cure or mitigate diseases, namely hypercholesterolemia and coronary heart disease, hypertension, diabetes, and immunodeficiency diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

LET403

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Please contact us if we may be of further assistance.

Sincerely,

John B. Foret  
Director  
Division of Compliance and Enforcement  
Office of Nutritional Products, Labeling,  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300  
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200  
FDA, Chicago District Office, Office of Compliance, HFR-MW140

cc:

HFA-224 (w/incoming)  
HFA-305 (docket 97S-0163)  
HFS-22 (CCO)  
HFS-800 (r/f, file)  
HFS-810  
HFS-811 (file)  
HFD-310  
HFD-314 (Aronson)  
HFS-605  
HFV-228 (Benz)  
GCF-1 (Dorsey, Nickerson)  
f/t:HFS-811:rjm:10/4/00:docname:72679.adv:disc51



**KT NATURAL PRODUCTS, INC.**

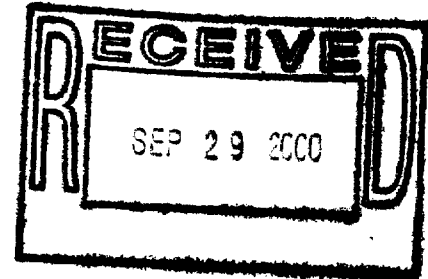
1528 Devonwood Drive  
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1-217-793-6443

Fax: 1-217-793-8050

September 20, 2000



Dr. Robert Moor  
Office of Special Nutritionals  
Regulatory Branch, Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
200 "C" Street S.W.  
HFS-456  
Washington, D.C. 20204

**RE: Master file document for MiracleHerb-GP™**

Dear Dr. Moor:

In accordance with 21 CFR 101.93, this letter and its accompanying documents will serve as notification that KT Natural Products, Inc., Springfield, Illinois, the manufacturer and distributor, is marketing MiracleHerb-GP™ brand standardized gypenosides from *Gynostemma pentaphyllum* as a dietary supplement.

The MiracleHerb-GP dietary supplement will utilize the following statements in its product literature:

- Tonic for restoring the body's overall balance and enhancing physiological performance.
- Promote healthy cardiovascular functions
  - Maintain normal cholesterol and triglyceride levels
  - Maintain a healthy blood pressure
  - Decrease vascular resistance and increase coronary blood flow
  - Reduce vascular plaque
- Maintain normal blood glucose level
- Promote healthy liver functions

- Preserve immunocompetence
- Provide extensive antioxidant protection for cells and biomembranes

These functional claims are supported by published peer reviewed scientific literatures. Papers describing the effects of the traditional Chinese herb, *Gynostemma pentaphyllum*, on human and non-human models have been published worldwide in different languages. The chemical constituents of the herb have been extensively characterized in current arts. Many of these constituents are identical to those found in the more familiar herb, ginseng.

Supporting evidence for the claims listed above is contained in the document that accompanies this letter. We are providing the agency with three copies of the document, as stipulated in 21 CFR 101.93. The manufacture requests that this information be entered into an FDA master file for reference.

Thank you very much for your consideration. The master file number can be sent to my attention at the address listed above.

Sincerely,

A handwritten signature in black ink, appearing to read 'Lin Yan', with a stylized, flowing script.

Lin Yan  
Scientific and Regulatory Affairs

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